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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3739

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10/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,292	Applicant(s) LEVEY ET AL.	
	Examiner MATTHEW J. KASZTEJNA	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8-10 and 12-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-10 and 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/7/8, 9/25/6</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “17” has been used to designate both a “distal end” and “proximal end” (see paragraphs 0023-0024). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance. As a result, there is confusion throughout the specification and claims as to the proximal end and the distal end of the apparatus. For example, as shown in Figures 1, 4-5, and 8, the first flange which prevents insertion into the body and contains the reservoir 12, is *not* located at a proximal end of the control device. However in independent claims 1 and 13, the first flange is said to be located closer to the proximal end thereof.

Claim Objections

Claim 1 is objected to because of the following informalities: the claim recites an “annular tube” having first and second flanges; however, it appears the claim should read an “outer tube” which has first and second flanges. Base upon the specification,

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paragraphs 019-020, the outer tube 10 is formed with first and second flanges and the annular tube 20 is positioned therethrough. This change is recommended to avoid confusion throughout the depended claims (i.e. claim 4) and to better define the invention with respect to the accompanying specification and figures. Appropriate correction is required.

Claim 17 is objected to because of the following informalities: the word "the" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 8-10, 12 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "endoscope control" in line 13 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 3-4, 8-10, 12 and 14-18 are rejected as being necessarily dependant upon claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 8-10, 12-16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0022762 to Beane et al.

In regard to claims 1 and 13, Beane et al. disclose a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity comprising: an annular tube 614 having an outer and inner surface with the inner diameter of the tube sized to permit sliding passage therethrough of the insertion end of an endoscope tube 16, a first flange 642 extending outwardly from the annular tube closer to the proximal end thereof, wherein the diameter of the first flange is sized to preclude insertion of the control into the body cavity of a patient (see paragraph 0094), a second flange extending outwardly from the annular tube closer to the distal end thereof (see Figs. 6a-b), said annular tube having means 628 for coating the endoscope tube as it passes through the annular tube with a lubricant wherein the first and second flanges act as barriers to prevent lubricant from migrating onto said endoscope control (see paragraphs 0087-0093). It is noted with regard to the limitation “means for coating the endoscope with a lubricant”, that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Furthermore, as broadly as claimed, saline solution is interpreted as a “lubricant”.

In regard to claims 3, 12, and 14, Beane et al. disclose a non-invasive external control, wherein said coating means comprises a compressible foam member

impregnated with a lubricant positioned to engage an endoscope tube as it moves through the control (see Fig. 6b and paragraphs 0091-0093).

In regard to claim 4, Beane et al. disclose a non-invasive external control wherein the foam member comprises an annular tube at least partially positioned at one end within the annular tube and having an inner uncompressed diameter substantially equal to the outer diameter of an endoscope tube intended to be controlled (see Fig. 6b and paragraphs 0091-0093).

In regard to claim 8, Beane et al. disclose a non-invasive external control, wherein the distance between the first and second flanges provide a sufficient length along the annular tube for hand-gripping (see Fig. 6b).

In regard to claims 9-10, Beane et al. disclose a non-invasive external control wherein said first flange has a passage extending radially from the inner surface of said annular tube outwardly through the annular flange, wherein said passage feeds a lubricant into the interior of the annular tube (see Fig. 6b).

In regard to claim 15, Beane et al. disclose a non-invasive external control, wherein the control has means 640 for opening the control along its length (see Fig. 6a and paragraph 0094).

In regard to claims 16 and 19, Beane et al. disclose a non-invasive external control, wherein said second flange is shaped for gripping to assist in controlling the insertion and removal of the endoscope tube (see Figs. 6a-b).

In regard to claims 18 and 20, Beane et al. disclose a non-invasive external, further comprising a reservoir 630 for holding the lubricant, wherein said reservoir is located within said first flange (see Fig. 6b and paragraph 0092).

Claims 1, 3-4, 8, 12-17, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,334,166 to Palestrant.

In regard to claims 1 and 13, Palestrant discloses a non-invasive external control for facilitating the insertion and removal of an endoscope into a body cavity comprising: an annular tube 42 having an outer and inner surface with the inner diameter of the tube sized to permit sliding passage therethrough of the insertion end of an endoscope tube (see Col. 9, Lines 49-51), a first flange 25 extending outwardly from the annular tube, wherein the diameter of the first flange is sized to preclude insertion of the control into the body cavity of a patient, a second flange (not labeled) extending outwardly from the annular tube (see Fig. 2), said annular tube having means 26 for coating the endoscope tube as it passes through the annular tube with a lubricant wherein the first and second flanges act as barriers to prevent lubricant from migrating onto said endoscope control (see Col. 9, Lines 40-67).

In regard to claims 3, 12, and 14, Palestrant discloses a non-invasive external control, wherein said coating means comprises a compressible foam member 26 impregnated with a lubricant positioned to engage an endoscope tube as it moves through the control (see Col. 10, Lines 60-65).

In regard to claim 4, Palestrant discloses a non-invasive external control wherein the foam member comprises an annular tube at least partially positioned at one

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end within the annular tube and having an inner uncompressed diameter substantially equal to the outer diameter of an endoscope tube intended to be controlled (see Fig. 2).

In regard to claim 8, Palestrant disclose a non-invasive external, wherein the distance between the first and second flanges provide a sufficient length along the annular tube for hand-gripping (see Figs. 2 and 5).

In regard to claim 15, Palestrant discloses a non-invasive external control, wherein the control has means 30 for opening the control along its length (see Fig. 1 and 6).

In regard to claims 16 and 19, Palestrant discloses a non-invasive external control, wherein said second flange is shaped for gripping to assist in controlling the insertion and removal of the endoscope tube (see Figs. 5 and 10c).

In regard to claims 17 and 21, Palestrant discloses a non-invasive external control, wherein said annular tube is compressible to control said means for coating the endoscope tube with a lubricant (see Col. 10, Lines 1-5).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J Kasztejna/
Primary Examiner, Art Unit 3739

10/22/09